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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/267,963	03/12/99	MIYAZONO	K LUD-5539.1-C
		HM22/0427	EXAMINER
			FITZGERALD, D
		ART UNIT	PAPER NUMBER
		1646	6
		DATE MAILED:	04/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/267,963	Applicant(s) MIYAZONO, et al.
Examiner David L. FITZGERALD	Group Art Unit 1646

Responsive to communication(s) filed on _____

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE (1) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-27 _____ is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-27 _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-11, drawn to nucleic acids encoding ALK-1 polypeptides (classified in Class 536/subclass 23.5) and the corresponding vectors (435/320.1), cells (435/325), and polypeptides (530/350).
 - 5 II. Claims 12 and 13, drawn to antibodies that bind to ALK-1 (530/388.22).
 - III. Claims 14-20 and 28, as they read on methods employing agents which inhibit Smad1 or Smad-5 phosphorylation (classification varying with the nature of the agent).
 - 10 IV. Claims 21-26 and 28, as they read on methods employing agents which promote Smad1 or Smad-5 phosphorylation (classification varying with the nature of the agent).
 - V. Claim 27, drawn to a phosphorylation assay involving coexpression of ALK-1 and Smad1 or Smad-5 (435/7.1+).

ELECTION OF SPECIES: With the election of group III or IV, applicant is further required to elect 15 a single species of Smad1 phosphorylation-promoting or -inhibiting agent identified in the disclosure.

The inventions are distinct, each from every other, for the following reasons.

The nucleic acids and polypeptides of group I are related to the antibodies of group II 20 insofar as the polypeptides will interact with the antibodies. The products are patentably distinct because each is materially and functionally different from the other. Furthermore, the polypeptides have other uses, *e.g.*, in the disclosed assays, and the antibodies may be made with other reagents, *e.g.*, peptide or whole-cell immunogens.

The methods of groups III, IV, and V are patentably distinct, each from every other, because they employ materially distinct products and process steps, and none of the methods as 25 claimed is required to practice any other.

The products of groups I and II are independent from the methods of groups III, IV, and V to the extent that the latter methods do not employ the former products. Where the methods do employ such products, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with 30 another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). Here the recombinant cells of group I may be alternatively used to inhibit the activity of TGF- β in a heterogeneous system, and the antibodies of group II may be alternatively employed in immunoassays of ALK-1 polypeptides.

This application contains claims within groups III and IV, as indicated above, which are directed to patentably distinct species of the claimed inventions, *viz.*, agents corresponding to the subgenera recited in the claims which depend from claims 14 and 21. With the election of either group III or IV, applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims of the elected invention shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 14, 21, and 28 are generic.

5 Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that 10 all claims are generic is considered nonresponsive unless accompanied by an election.

15 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

20 Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission 25 may be used in a rejection under 35 U.S.C. § 103 of the other invention.

These inventions are distinct for the reasons given above and have acquired separate status in the art, as shown by their different classifications and because they would entail divergent 25 searches of the research literature and consideration of unique issues of patentability. Examination of the plural inventions would accordingly constitute an undue burden upon the Office, and restriction for examination purposes as indicated is thus proper.

30 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

2. Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax

All formal papers (703) 308-4242

Informal communications (703) 308-0294

e-mail (note PTO policies below) david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1600 receptionists at (703) 308-0196.



DAVID L. FITZGERALD
PRIMARY EXAMINER
ART UNIT 1646

26 April 2000

The best time to reach **Examiner Fitzgerald** is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the supervisor for this Art Unit, Gary Kunz, may be reached at (703) 308-4623.

Most official papers and all informal **communications may be submitted to the PTO by fax**. For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- ♦ Call the examiner when you send an urgent communication.
- ♦ **Do not send a duplicate copy by mail or courier.**

Any Internet e-mail **communications will be made of record in the application file**. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.